

Exhibit B



Deposition of:
David Kessler , M.D.

October 5, 2016

In the Matter of:
Clare-Austin vs. C.R. Bard

Tiffany Alley, A Veritext Company

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1 Julia has an associate, Laura Smith, in her firm. I
2 believe Ramon, you have an associate, Nicholas --

3 MR. LOPEZ: Graham.

4 THE WITNESS: -- Graham. I'm not sure I've
5 met -- been in the same room as Nicholas. I've talked
6 to Nicholas.

7 MR. LOPEZ: He's going to be happy his name is
8 on the transcript.

9 BY MR. NORTH:

10 Q. Prior to the time you were contacted by
11 Mr. Cartmell to become involved in this litigation, had
12 you had any professional involvement with inferior vena
13 cava filters?

14 MR. LOPEZ: I'll object as to form.

15 THE WITNESS: So I have one, one recollection,
16 I mean, that is in my memory. Obviously, I mean, with
17 regard to the 1990s, we have to check the records to see
18 whether ExecSec has records of my being involved in vena
19 cava filters. I just don't have a recollection sitting
20 here today.

21 But there is one other -- what was the actual
22 question you asked? Have you had any professional
23 involvement, I think, was the way you phrased it. So I
24 want to be careful here because I don't want to breach
25 any lawyer-attorney work product here. But I think it's

1 fair to say I was approached -- I was approached by NBC
2 lawyers, I was approached to explain to NBC lawyers the
3 regulatory framework for medical devices, and
4 specifically inferior vena cava filters. I have
5 a recollection of that.

6 BY MR. NORTH:

7 Q. Was that in connection with the NBC broadcast
8 regarding Bard filters?

9 A. I believe it was prior to that, sir. I believe
10 I -- my recollection is I got a phone call and asking if
11 I could explain to lawyers how medical devices and
12 inferior vena cava filters were regulated under federal
13 law. I have a recollection of that, I have a
14 recollection of doing that.

15 Q. Do you recall the time frame generally when
16 that contact was made?

17 A. It was a number of years ago. It was prior to
18 the broadcast, I believe. I don't have a specific date
19 in my head.

20 Q. So was it -- the broadcasts were in 2015. Was
21 it prior to 2015?

22 A. Do you know when in 2015 the broadcast --

23 Q. July was the first -- no, September was the
24 first one and December the second one.

25 A. I wouldn't want to -- I mean, I'm under oath.

1 it's the manufacturer that has the responsibility to
2 assure safety. 510(k) is not a -- I mean, it's evolved,
3 I guess, and, you know, FDA can at certain points for
4 certain reasons ask for additional studies, but it's
5 not -- it's not a review of safety and effectiveness.

6 Q. The 1990 Act also added some special controls
7 governing Class 2 devices, didn't it?

8 A. Yes. For example, the guidance that you raised
9 in 1999 were in fact special controls -- right? -- so
10 they were, in essence, performance standards that had
11 to be met. But they were really part -- performance
12 standards were always contemplated to be part of Class 2
13 devices.

14 Can I just see the 1999 one more second? I
15 want to double-check myself and make sure I didn't
16 misspeak.

17 MR. LOPEZ: Sure.

18 THE WITNESS: So I just want to make sure. I'm
19 sorry, this is not -- I don't see any of them, I'm
20 sorry. Give me one more second.

21 So here it is. So -- I apologize.
22 There is -- I just want to get the exact quote in
23 double-checking myself. I'm pretty sure it says
24 migration has to be reported greater than five, when
25 there's migration greater than five millimeters -- if

1 someone can help me see where that is in the document?

2 Does anyone know what page that's on?

3 So here it is. Let me not waste your time, but
4 if someone can help me see if there's greater than five
5 millimeter increments? I thought I remembered that.

6 I apologize.

7 BY MR. NORTH:

8 Q. Do you intend to offer an opinion in this case
9 that the G2 filter is defectively designed?

10 A. That's what -- I don't want to use the
11 term -- I mean, I don't know if that's a legal
12 conclusion.

13 What I did -- I mean, G2 was adulterated, okay?
14 G2 did not pass the caudal migration testing. And I
15 checked -- I just checked at lunch just to add -- you
16 asked me about Austin and tilt, and, I mean, she's a
17 classic case. But the radiological report there, you
18 asked me about tilt. The radiological report, I think
19 on 11-13 2013, 11-19 2013 --

20 THE REPORTER: I'm sorry, doctor. The date?

21 THE WITNESS: It was either 11-13 or 11-19 -- I
22 can pull it up in a second -- 2013, said the filter was
23 horizontal. So you don't need to be a radiologist to
24 know that horizontal is not just a little tilt but is
25 reported as horizontal.

1 But G2 failed its caudal migration test. It
2 actually failed the migration resistance test -- Bard
3 changed the standards -- but it was represented as
4 having greater stability. It clearly failed caudal
5 migration and, therefore, it was adulterated. So
6 obviously, again, obviously it was defective. It was
7 also -- should have never been on the market also
8 because Recovery was -- should have never been on the
9 market and Recovery was the predicate. Recovery should
10 have been taken off way before the G2 came on and the G2
11 would not have had a predicate.

12 So it was adulterated, I think is probably the
13 right way for me to say it. It certainly was -- there
14 was evidence that it failed to maintain its standard --
15 right? -- of, I mean, increased stability. It was
16 not -- it had greater caudal migration in G2 than RNF
17 and SNF and failed in performance. The exact defect
18 that Clare Austin had -- not defect, the adverse event
19 that she had, so it was clearly defective.

20 Q. So it your testimony that the filter in
21 Ms. Austin caudally migrated?

22 A. I believe it caudally migrated. Others can
23 testify to that. It's certainly horizontal, I believe
24 it caudally migrated, that was my impression from the
25 medical record, but I'll let other doctors talk about